



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2012-0005]

**Recommendations for the Identification of Hepatitis C Virus
(HCV) Chronic Infection**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces draft recommendations for identification of persons with HCV chronic infection, available for public comment. The recommendations are intended to increase the proportion of persons with chronic HCV who are diagnosed, provided appropriate prevention services, and linked to needed care and treatment. Public comment will be used to inform the final recommendations. The *Recommendations* may be found at <http://www.regulations.gov>, Docket No. CDC-2012-0005.

DATES: Written comments must be received on or before June 8th, 2012.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2012-0005, by any of the following methods:

- *Internet:* Access the Federal eRulemaking portal at <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Mailstop G-37, Atlanta, Georgia 30333.

Instructions: All submissions received must include the agency name and docket number for this notice. All relevant comments will be posted without change to <http://www.regulations.gov> including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>, Docket No. CDC-2012-0005.

FOR FURTHER INFORMATION CONTACT: Rebecca Morgan, Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and

Prevention, 1600 Clifton Road, Mailstop G-37, Atlanta, Georgia 30333. You may also call 404-718-8596 or send an email to HCV_BC@cdc.gov.

SUPPLEMENTARY INFORMATION:

Hepatitis C virus infection is a contagious liver disease that ranges in severity from a mild illness lasting a few weeks to a serious, lifelong illness. It results from infection with the hepatitis C virus (HCV), which is spread primarily through contact with the blood of an infected individual. In approximately 75%-85% of persons, HCV persists as a chronic infection, which places infected persons at risk for liver cirrhosis, liver cancer or hepatocellular carcinoma (HCC), and complications involving other organ systems that develop over the decades following onset of infection. HCV infection status is determined by a blood test.

In the United States an estimated 2.7-3.9 million persons are living with HCV infection. Cirrhosis, HCC and HCV-related mortality have been increasing among persons infected with HCV, and these outcomes are projected to increase significantly in the coming decades. HCV-infected persons who are aware of their infection can benefit from health services to prevent additional harm to the liver (e.g., hepatitis A virus and hepatitis B virus vaccination), medical monitoring, and behavioral changes (e.g.,

reductions in alcohol use). Further, anti-viral therapies can clear HCV from the system (i.e., a virologic cure) and halt disease progression for many patients living with HCV infection.

CDC is seeking public comment on these *Recommendations*, particularly concerning the following questions:

- 1) Are there other data, evidence, or studies to consider regarding:
 - a. the burden of HCV infection morbidity, and mortality in the populations for whom testing is recommended?
 - b. the number of persons living with HCV who are unaware of their infection status?
 - c. the benefits and harms of HCV testing, care and treatment?
 - d. the cost effectiveness of the proposed recommendations?
 - e. settings in a community where testing should be targeted?
- 2) Are there other factors, e.g., other scientific studies not referenced, which should be considered in the development of the *Recommendations*?

3) Are there any other comments about the utility of the
information?

Dated: May 15, 2012

Tanja Popovic, MD, PhD, F(AMM), AM(AAFS)
Deputy Associate Director for Science
Centers for Disease Control and Prevention

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